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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/749,339	12/31/2003	Larry Augsburg	11478-014-999	9882
20583	7590	05/19/2009		
JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017			EXAMINER SILVERMAN, ERIC E	
			ART UNIT	PAPER NUMBER
			1618	
			MAIL DATE	DELIVERY MODE
			05/19/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/749,339	Applicant(s) AUGSBURGER ET AL.	
	Examiner ERIC E. SILVERMAN	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/15/2009 has been entered.

Claims 1-11 are pending in this action; all claims are treated on the merits.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-11 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 16-30 of U.S. Patent No. 5,780,055 in view of US 4,910,023 for reasons of record and those discussed below.

Claim Rejections - 35 USC § 102

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-11 remain rejected under 35 U.S.C. 102(b) as being anticipated by Mount et al. for reasons of record and those discussed below.

Claims 1-11 remain rejected under 35 U.S.C. 102(a) as being anticipated by Botzolakis for reasons of record and those discussed below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-11 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Botzolakis in view of Habib for reasons of record and those discussed below.

Response to Arguments

Applicant's arguments filed 4/15/2009 have been fully considered but they are not persuasive. Applicants argue that Mount does not teach freeze-drying, and that the Mount particles cannot withstand a compression force as high as 1,000 kg during a tableting process. In response, Mount discloses at the paragraph bridging pages 616 and 617 that "the tablets made from all formulations containing MCC powder were harder than could be tested with the apparatus, being harder than 13.0 kg." This means that the particles of Mount having MCC can withstand these forces. While Mount does not look at compression higher than 13.0 kg (presumably because Mount lacked the equipment to conduct such tests). While this does not conclusively show that the prior art oven dried particles can withstand up to 1,000 kg it does lend any support to Applicants' contention that the particles of Mount could not withstand higher forces. On the contrary, there are good technical reasons to believe that there are no differences between the freeze-drying of instant claims and oven-drying in Mount. The primary difference between lyophilization (freeze-drying) and oven drying is that the former can remove all detectable amounts of water, whereas the latter leaves detectable amounts of water even when drying is "complete." However, instant claims require that water be present in the placebo cushioning particles. Therefore, this difference is not relevant to

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the invention described in the claims. Further, Mount achieves a demonstrable and acceptable cushioning effect with oven dried particles.

The evidence of record does not show any difference between oven-dried and freeze dried particles. The particles of the Mount contain the same ingredients as those of the claims. This provides a reasonable basis for the conclusion that the particles of Mount have the same salient features as those of the claims.

With respect to Botzolakis, Applicants also allege oven drying does not produce the particles of instant claims. The evidence of record does not support this position, for reasons discussed above. Applicants' arguments are therefore unpersuasive.

Applicants are reminded that when the Examiner has provided a reason why the prior art inherently possess a feature of the claimed invention, the burden shifts to Applicant to demonstrate that the feature is not inherent. The office may require that the Applicant provide evidence, or point to evidence already of record, to make such a showing. Applicants have not explained why the evidence supports their position, and so their arguments are unpersuasive.

With respect to the obviousness rejection and the obviousness-type double patenting rejection, Applicants' arguments regarding Habib's teaching of freeze drying cannot be persuasive without evidence indicating that freeze dried particles are different from oven-dried particles.

Applicants' statement that "Habib teaches freeze-drying of the cushioning component alone prior to combining it with the biologically active ingredient loaded beads [citations omitted]. Habib does not teach or suggest freeze-drying of the

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admixture of cushioning component and biologically active ingredient-loaded beads" is not well understood for two reasons. First, Applicants do not explain why there would be any difference between freeze drying the beads separately and then combining them, as in Habib, or first mixing the beads and then freeze-drying them. Even if freeze-drying produces some benefit that is not recognized by the prior art, applicants "recogni[tion of] another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious." MPEP 2145 (quoting *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). Second, Applicants' comments might be interpreted to mean that the claims require that the "placebo" cushioning beads also have active agent in them. The claims as written, however, neither require nor forbid active agent to be in the cushioning beads. The claims require two types of beads: one with active agent, and a second cushioning bead. The first must have active agent, the second need not (though the claims do not forbid inclusion of active in the cushioning beads). If Applicants intended the claims to mean something else, further clarification or amendment would be helpful.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERIC E. SILVERMAN whose telephone number is (571)272-5549. The examiner can normally be reached on Monday to Thursday 7:00 am to 5:00 pm and Friday 7:00 am to noon.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571 272 0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric E Silverman/
Examiner, Art Unit 1618